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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/463,097	01/18/00	ZIMMERMANN	J 4-30096/A

001095
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EXAMINER

BERNHARDT, E

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/28/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-12 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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Claims 1- 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. What is the scope of “essentially dry” in main claim 1. Also what is being excluded from the scope of claim 8 where “essentially” is also recited?

2. Claims 4-8 are not seen to materially differ from each other since for claims 4,5,7,8 the same compound is being claimed with the same purity requirement but only further characterized in terms of X-ray diffraction data and/or other structure determination techniques. Claim 6 is not seen to further limit claim 1 based solely on X-ray diffraction ^{data} ~~peak~~ recited therein.

3. For process claim 12, the same reaction conditions are recited for both digesting and dissolving the starting reactant and thus seems to be reciting one process rather than two. Clarification is requested.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9 and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims drafted in terms of “use” have been held to be non-statutory. Note *Clinical products v. Brenner* 149 USPQ 475.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmermann (US, provided by applicants).

Zimmermann describes the free form of instant compound along with a list of intended salts including the methanesulfonate salt. See eg. 21 and claim 23. The list of 32 recited salts in col. 3 coupled with claim 23 constitutes an anticipation of the methanesulfonate salt in view of the narrow genus present. See *In re Petering* 133 USPQ 275; *In re Schaumann* 197 USPQ 5; *In re Sivaramakrishnan* 213 USPQ 441 regarding anticipation requirements. It is recognized that applicants are claiming a specific crystalline form and while Zimmermann is silent as to the existence of one or more forms for its salts, applicants must show that employing routine procedures for making the Ms salt as relied on by Zimmermann (see col. 19), the instant beta form is not inherently produced. See *In re Fitzgerald* 205 USPQ 594; and *In re Grose* 201 USPQ 57.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Zimmermann.

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If the genus is deemed too large to place the instant mesylate salt in the public's possession, it is otherwise an obvious variant in view of the express teaching to employ said salt among others for the uses taught for the free form. See last paragraph in col.3 and first one in col.4. Thus it would have been obvious to one skilled in the art at the time the invention was made to employ instant mesylate salt for use as an anti-tumor agent in view of the equivalency teaching outlined above. The same comment made above for overcoming the 102 rejection also applies herein.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmermann in view of Yu (applied as of its effective filing date). The teachings of Zimmermann as discussed in the above 102 and 103 rejections are incorporated herein. Yu is applied to show that polymorphic forms are frequently encountered for pharmaceuticals and that the desired form (eg. less hygroscopic) can often be obtained a number of ways including the dissolution of other forms in various solvents including methanol. See col.5 last paragraph which discusses dissolution of form I to obtain form III which is collected by filtration. Thus instant process step is an obvious expedient and involves no more than routine skill to arrive at the desired form.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

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A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600 / 600